TRILYTE WITH FLAVOR PACKS - polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride powder, for solution

Alaven Pharmaceutical LLC

(PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution)

Rx Only

DESCRIPTION

TRILYTE is a white powder for reconstitution containing 420 g polyethylene glycol 3350, 5.72 g sodium bicarbonate, 11.2 g sodium chloride, 1.48 g potassium chloride. Flavor packs, each containing 3.22 g of flavoring ingredients, are attached to the 4 liter bottle. See individual flavor packs for complete listing of ingredients. When dissolved in water to a volume of 4 liters, TRILYTE with flavor packs (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) is an isosmotic solution, for oral administration, having a pleasant mineral water taste. One flavor pack can be added before reconstitution to flavor the solution. TRILYTE with flavor packs is administered orally or via nasogastric tube as a gastrointestinal lavage. This preparation can be used without the addition of a flavor pack.

CLINICAL PHARMACOLOGY

TRILYTE with flavor packs induces a diarrhea which rapidly cleanses the bowel, usually within four hours. The osmotic activity of polyethylene glycol 3350 and the electrolyte concentration result in virtually no net absorption or excretion of ions or water. Accordingly, large volumes may be administered without significant changes in fluid or electrolyte balance.

INDICATIONS AND USAGE

TRILYTE with flavor packs is indicated for bowel cleansing prior to colonoscopy.

CONTRAINDICATIONS

TRILYTE with flavor packs is contraindicated in patients known to be hypersensitive to any of the components. TRILYTE with flavor packs is contraindicated in patients with ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon.

WARNINGS

The flavor packs are for use with the accompanying 4 liter bottle. No additional ingredients, e.g., flavorings, should be added to the solution. TRILYTE with flavor packs should be used with caution in patients with severe ulcerative colitis. Use of TRILYTE with flavor packs in children younger than 2 years of age should be carefully monitored for occurrence of possible hypoglycemia, as this solution has no caloric substrate. Dehydration has been reported in 1 child and hypokalemia has been reported in 3 children.

PRECAUTIONS

General

Patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration should be observed during the administration of TRILYTE with flavor packs, especially if it is administered via nasogastric tube. If a patient experiences severe bloating, distention or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abate. If gastrointestinal obstruction or perforation is suspected, appropriate studies should be performed to rule out these conditions before administration of TRILYTE with flavor packs.

Information For Patients

TRILYTE with flavor packs produces a watery stool which cleanses the bowel prior to examination. Prepare the solution according to the instructions on the bottle. It is more palatable if chilled. For best results, no solid food should be consumed during the 3 to 4 hour period before drinking the solution, but in no case should solid foods be eaten within 2 hours of taking TRILYTE with flavor packs. Adults drink 240 mL (8 oz.) every 10 minutes. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters. Any unused portion should be discarded. Pediatric patients (aged 6 months or greater) drink 25 mL/kg/hour. Continue drinking until the watery stool is clear and free of solid matter. Any unused portion should be discarded. Rapid drinking of each portion is better than drinking small amounts continuously. The first bowel movement should occur approximately one hour after the start of TRILYTE with flavor packs administration. You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occurs, stop drinking temporarily or drink each portion at longer intervals until these symptoms disappear.

Use of TRILYTE with flavor packs in children younger than 2 years of age should be carefully monitored for occurrence of possible hypoglycemia, as this solution has no caloric substrate. Dehydration has been reported in 1 child and hypokalemia has been reported in 3 children.

Drug Interactions
Oral medication administered within one hour of the start of administration of TRILYTE with flavor packs may be flushed from the gastrointestinal tract and not absorbed.

Carcinogenesis, Mutagenesis, Impairment Of Fertility
Carcinogenic and reproductive studies with animals have not been performed.

Pregnancy

Category C
Animal reproduction studies have not been conducted with TRILYTE with flavor packs. It is also not known whether TRILYTE with flavor packs can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. TRILYTE with flavor packs should be given to a pregnant woman only if clearly needed.

Pediatric Use
Safety and effectiveness of TRILYTE with flavor packs in pediatric patients aged 6 months and older are supported by evidence from adequate and well-controlled clinical trials of a similar product in adults with additional safety and efficacy data from published studies of similar formulations.

ADVERSE REACTIONS
Nausea, abdominal fullness and bloating are the most common adverse reactions (occurring in up to 50% of patients) to administration of TRILYTE with flavor packs. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient and subside rapidly. Isolated cases of urticaria, rhinorrhea, dermatitis, and (rarely) anaphylactic reaction have been reported which may represent allergic reactions.
Published literature contains isolated reports of serious adverse reactions following the administration of PEG-ELS products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallory-Weiss Tear, esophageal perforation, asystole, sudden dyspnea with pulmonary edema, and "butterfly-like" infiltrate on chest X-ray after vomiting and aspirating PEG.

DOSAGE AND ADMINISTRATION
TRILYTE with flavor packs is usually administered orally, but may be given via nasogastric tube to patients who are unwilling or unable to drink the solution. Ideally, the patient should fast for approximately three or four hours prior to TRILYTE with flavor packs administration, but in no case should solid food be given for at least two hours before the solution is given.

Oral Administration
Adults: At a rate of 240 mL (8 oz.) every 10 minutes, until the rectal effluent is clear or 4 liters are consumed. **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear. Rapid drinking of each portion is preferred to drinking small amounts continuously. **Nasogastric Tube Administration: Adults:** At a rate of 20-30 mL per minute (1.2-1.8 liters per hour). **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear.
The first bowel movement should occur approximately one hour after the start of TRILYTE with flavor packs administration. Ingestion of 4 liters of TRILYTE with flavor packs solution prior to gastrointestinal examination produces satisfactory preparation in over 95% of patients.
Various regimens have been used. One method is to schedule patients for examination in midmorning or later, allowing the patients three hours for drinking and an additional one hour period for complete bowel evacuation. Another method is to administer TRILYTE with flavor packs on the evening before the examination.

Preparation of the Solution
This preparation can be used with or without the flavor packs. The pharmacist should dispense the bottle and the attached flavor packs to the patient.
1. To add flavor, tear open one flavor pack at the indicated marking and pour contents into the bottle BEFORE reconstitution. Discard unused flavor packs.

2. SHAKE WELL to incorporate flavoring into the powder.

3. Add tap water to FILL line marked 4 liters. Replace cap tightly and SHAKE WELL until all ingredients have dissolved. No additional ingredients, e.g., flavorings, should be added to the solution.

Note: If not using a flavor pack, omit steps one and two above.
Dissolution is facilitated by using lukewarm water. The solution is more palatable if chilled before administration. However, chilled solution is not recommended for infants. The reconstituted solution should be refrigerated and used with 48 hours. Discard any unused portion.

HOW SUPPLIED

TRILYTE with flavor packs (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) is supplied in a 4 liter bottle with an attached package containing flavor packs. This preparation is supplied in powdered form (white to off-white powder) for oral administration as a solution following reconstitution. Each 4 liter bottle contains polyethylene glycol 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g. Each flavor pack contains 3.22 g of flavoring ingredients. When made up to 4 liters volume with water, the solution contains PEG-3350 31.3 mmol/L, sodium 65 mmol/L, chloride 53 mmol/L, bicarbonate 17 mmol/L and potassium 5 mmol/L.

TRILYTE with flavor packs	4 liter	NDC 68220-131-04

Rx Only

STORAGE

Store in sealed container at 25°C (77°F); excursions permitted between 15° - 30° C (59° - 86°F). When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.

Manufactured for ALAVEN Pharmaceutical LLC, Marietta, GA, USA
For Medical Inquiries, call toll-free 1-888-317-0001
TRILYTE is a registered trademark of SRZ Properties, Inc.

PRINCIPAL DISPLAY PANEL - 4 LITER BOTTLE LABEL

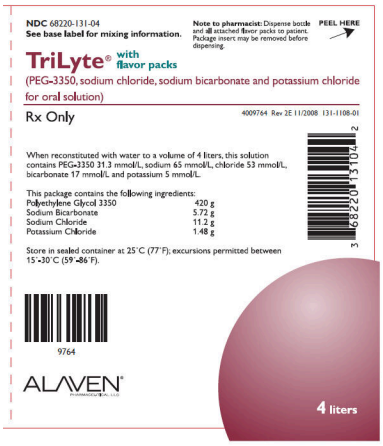
NDC 68220-131-04
See base label for mixing information.
Note to pharmacist: Dispense bottle
and all attached flavor packs to patient.
Package insert may be removed before
dispensing.

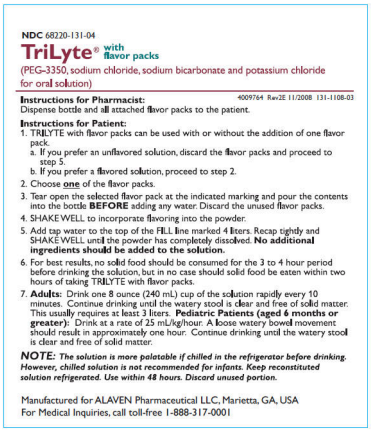
TriLyte®
with
flavor packs
(PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride
for oral solution)
Rx Only
4009764 Rev 2E 11/2008 131-1108-01
When reconstituted with water to a volume of 4 liters, this solution
contains PEG-3350 31.3 mmol/L, sodium 65 mmol/L, chloride 53 mmol/L,
bicarbonate 17 mmol/L and potassium 5 mmol/L.
This package contains the following ingredients:

Polyethylene Glycol 3350	420 g
Sodium Bicarbonate	5.72 g
Sodium Chloride	11.2 g
Potassium Chloride	1.48 g

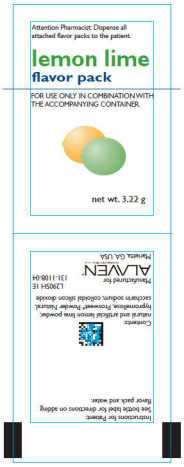
Store in sealed container at 25°C (77°F); excursions permitted between
15°-30°C (59°-86°F).

ALAVEN®
PHARMACEUTICAL LLC
4 liters





PRINCIPAL DISPLAY PANEL - LEMON LIME FLAVOR PACK LABEL
Attention Pharmacist: Dispense all
attached flavor packs to the patient.
lemon lime
flavor pack
FOR USE ONLY IN COMBINATION WITH
THE ACCOMPANYING CONTAINER.
net wt. 3.22 g

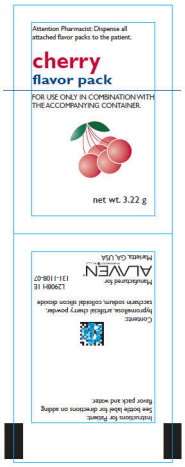


PRINCIPAL DISPLAY PANEL - PINEAPPLE FLAVOR PACK LABEL
Attention Pharmacist: Dispense all
attached flavor packs to the patient.
pineapple
flavor pack
FOR USE ONLY IN COMBINATION WITH

THE ACCOMPANYING CONTAINER.
net wt. 3.22 g

PRINCIPAL DISPLAY PANEL - CITRUS BERRY FLAVOR PACK LABEL
Attention Pharmacist: Dispense all
attached flavor packs to the patient.
citrus berry
flavor pack
FOR USE ONLY IN COMBINATION WITH
THE ACCOMPANYING CONTAINER.
net wt. 3.22 g

PRINCIPAL DISPLAY PANEL - CHERRY FLAVOR PACK LABEL
Attention Pharmacist: Dispense all
attached flavor packs to the patient.
cherry
flavor pack
FOR USE ONLY IN COMBINATION WITH
THE ACCOMPANYING CONTAINER.
net wt. 3.22 g



PRINCIPAL DISPLAY PANEL - ORANGE FLAVOR PACK LABEL

Attention Pharmacist: Dispense all
attached flavor packs to the patient.

orange

flavor pack

FOR USE ONLY IN COMBINATION WITH
THE ACCOMPANYING CONTAINER.

net wt. 3.22 g